

10/774,903

Sheet 1 of 1

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Attorney Docket Number 9233.74 CT		Serial No. 10/018,879 To be assigned	
				Applicants: Ekwuribe et al.			
				Filing Date: August 5, 2002 Concurrently benefit		Group Art Unit: 1654	
U. S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
JR	1.	Bone et al. "Successful Treatment of an Insulin Dependent Rat Model of Human Type I Diabetes with Orally Active Insulin" Program and Abstracts, 4 th International Workshop on Lessons from Animal Diabetes, Omiya, Japan November 1994 (Abstract)					
JR	2.	Bone et al. "Successful Treatment of Type 1 Diabetes with Orally-Active Insulin: Studies in The Insulin Dependent BB/S Rat" Program and Abstracts, 55 th Annual Meeting of the American Diabetes Association, Atlanta Georgia, June 1995 (Abstract)					
JR	3.	Ekwuribe et al. "Oral Insulin Delivery: Hydrolyzable Amphiphilic Oligomer Conjugates Prolong Glucose Reduction" Proceed. Int'l. Symp. Control. Rel. Bioact. Mater. 26:147-148 (1999)					
JR	4.	Ekwuribe, Nnochiri "Conjugation-Stabilized Polypeptide Compositions, Therapeutic Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" <i>Biotechnology Advances</i> 14(4):575-576 (1996) (Abstract)					
JR	5.	Radhakrishnan et al. "Chemical Modification of Insulin with Amphiphilic Polymers Improves Intestinal Delivery" <i>Proceed. Intl. Symp. Control. Rel. Bioact. Mater.</i> 25:124-125 (1998) (Abstract)					
JR	6.	Radhakrishnan et al. "Oral Delivery of Insulin: Single Selective Modification at B29-LYS With Amphiphilic Oligomer" Program and Abstracts, 1999 National Meeting of the Ameri. Assoc. Pharm. Scient., New Orleans, LA (1999) (Abstract)					
JR	7.	Radhakrishnan et al. "Structure-Activity Relationship of Insulin Modified with Amphiphilic Polymers" Program and Abstracts, 1998 National Meeting of the Amer. Assoc. Pharm. Scient., San Francisco, CA <i>Pharm. Sci.</i> 1(1):S-59 (1998) (Abstract)					

EXAMINER Jeffrey E. RusselDATE CONSIDERED July 18, 2005

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Substitute form 1449A/PTO				Complete if Known					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10,010,879 To be assigned				
				Filing Date	August 5, 2002 <i>Concurrently herewith</i>				
				First Named Inventor	Ekwuribe				
				Group Art Unit	1654				
				Examiner Name	Russel, Jeffrey E.				
Sheet	1	Of	1	Attorney Docket Number	9233.746T				
U.S. PATENT DOCUMENTS									
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear			
		Number	Kind Code (if known)						
<i>JE</i>	1.	4,223,163		Guilloty	09/16/1980	568/618			
<i>JE</i>	2.	4,801,575		Pardridge	01/31/1989	514/4			
<i>JE</i>	3.	5,099,074		Mueller et al.	03/24/1992	568/617			
<i>JE</i>	4.	5,122,614		Zalipsky	06/16/1992	548/520			
<i>JE</i>	5.	5,298,410		Phillips et al.	03/29/1994	435/188			
<i>JE</i>	6.	5,320,840		Camble et al.	06/14/1994	424/85.1			
<i>JE</i>	7.	5,428,128		Mensi-Fattohi et al.	06/27/1995	530/302			
<i>JE</i>	8.	5,643,575		Martinez et al.	07/01/1997	424/194.1			
<i>JE</i>	9.	5,714,639		Bowman et al.	02/03/1998	568/620			
<i>JE</i>	10.	6,011,008		Domb et al.	01/04/2000	514/8			
FOREIGN PATENT DOCUMENTS						<i>Class/Subclass</i>			
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T	
		Office	Number	Kind Code (if known)					
<i>JE</i>	11.	JP	01207320		Daicel Chem Ind. Ltd.	08/21/1989	—		
<i>JE</i>	12.	JP	01254699		Kodama Co., Ltd.	10/11/1989	—		
<i>JE</i>	13.	PCT	WO 97/14740		Receptagen Corporation, University of Washington	04/24/1997	—		
<i>JE</i>	14.	EP	0 822 218 A2		Glenn A. Miller, Michael W. Jorgenson, Richard Budnik	02/04/1998	—		
<i>JE</i>	15.	DE	196 32 440 A1		BASF AG	02/19/1998	—		
<i>JE</i>	16.	PCT	WO 01/12230		Myung-Ok Park, Kang Choon Lee	02/22/2001	—		
OTHER NON PATENT LITERATURE DOCUMENTS									
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published							T
<i>JE</i>	17.	Hashimoto et al., "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities," <i>Pharmaceutical Research</i> , 6:2 171-176 (1989)							
<i>JE</i>	18.	Krishnan, B. Radha, et al., "Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2)," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 27 pp. 1038-39 (2000)							
<i>JE</i>	19.	Xia, Jiding, et al., "Effects of polyoxyethylene chain length distribution on the interfacial properties of polyethylene glycol n-dodecyl ether," <i>Yingyong Huaxue</i> , 2:4, pp. 59-65 (1985) (Abstract Only)							

Examiner Signature	Jeffrey E. Russel	Date Considered	July 18, 2005
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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)	Attorney Docket Number 9233-74CT	Serial No. 10/018,579 be assigned
	Applicants: Ekwuribe et al.	
	Filing Date: August 5, 2002 Concurrently herewith	Group

U. S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
JR	1.	3,919,411	11/11/75	Glass et al.	424	78,27	
JR	2.	3,950,517	04/13/76	Lindsay et al.	514	3	
JR	3.	4,253,998	03/03/81	Sarantakis	525	54,11	
JR	4.	4,277,394	07/07/81	Fujino et al.	530	303	
JR	5.	4,338,306	07/06/82	Kitao et al.	514	4	
JR	6.	4,348,387	09/07/82	Brownlee et al.	514	4	
JR	7.	4,469,681	09/04/84	Brownlee et al.	514	4	
JR	8.	4,472,382	09/18/84	Labrie et al.	514	15	
JR	9.	4,554,101	11/19/85	Hopp	514	17	
JR	10.	4,579,730	04/01/86	Kidron et al.	514	3	
JR	11.	4,839,341	06/13/89	Massey et al.	514	4	
JR	12.	4,917,888	04/17/90	Katre et al.	424	85,91	
JR	13.	4,957,910	09/18/90	Sutton et al.	514	182	
JR	14.	4,994,439	02/19/91	Longenecker et al.	514	3	
JR	15.	5,089,261	02/18/92	Nitecki et al.	424	85,2	
JR	16.	5,157,021	10/20/92	Balschmidt et al.	514	3	
JR	17.	5,162,430	11/10/92	Rhee et al.	525	54,1	
JR	18.	5,202,415	04/13/93	Jonassen et al.	530	303	
JR	19.	5,206,219	04/27/93	Desai	514	3	
JR	20.	5,283,236	02/01/94	Chiou	514	2	
JR	21.	5,286,637	02/15/94	Veronese et al.	514	2	
JR	22.	5,292,802	03/08/94	Rhee et al.	525	54,1	
JR	23.	5,304,473	04/19/94	Belagaje et al.	435	69,7	
JR	24.	5,308,889	05/03/94	Rhee et al.	525	54,1	
JR	25.	5,312,808	05/17/94	Shorr et al.	514	6	

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LIST OF DOCUMENTS CITED BY APPLICANT							
(Use several sheets if necessary)							
Applicants: Ekwuribe et al.							
Filing Date: August 5, 2002 Concurrently herewith						Group	
JRL	26.	5,324,775	06/28/94	Rhee et al.	525	54.2	
JRL	27.	5,328,955	07/12/94	Rhee et al.	525	54.1	
JRL	28.	5,405,621	04/11/95	Sipos	424	490	
JRL	29.	5,405,877	04/11/95	Greenwald et al	514	772.3	
JRL	30.	5,413,791	05/09/95	Rhee et al.	424	422	
JRL	31.	5,415,872	05/16/95	Sipos	424	490	
JRL	32.	5,444,041	08/22/95	Owen et al.	514	2	
JRL	33.	5,446,091	08/29/95	Rhee et al.	525	54.1	
JRL	34.	5,457,066	10/10/95	Frank et al.	435	68.1	
JRL	35.	5,461,031	10/24/95	De Felippis	514	4	
JRL	36.	5,468,478	11/21/95	Saifer et al.	424	78.27	
JRL	37.	5,504,188	04/02/96	Baker et al.	530	304	
JRL	38.	5,506,203	04/09/96	Backstrom et al.	514	4	
JRL	39.	5,518,998	05/21/96	Backstrom et al.	514	3	
JRL	40.	5,523,348	06/04/96	Rhee et al.	525	54.1	
JRL	41.	5,529,915	06/25/96	Phillips et al.	435	188	
JRL	42.	5,550,188	08/27/96	Rhee et al.	525	54.1	
JRL	43.	5,567,422	10/22/96	Greenwald	424	78.3	
JRL	44.	5,612,460	03/18/97	Zalipsky	530	391.9	
JRL	45.	5,631,347	05/20/97	Baker et al.	530	303	
JRL	46.	5,637,749	06/10/97	Greenwald	558	6	
JRL	47.	5,646,242	07/08/97	Baker et al.	530	303	
JRL	48.	5,650,388	07/22/97	Shorr et al.	514	6	
JRL	49.	5,658,878	08/19/97	Backstrom et al.	514	3	
JRL	50.	5,700,904	12/23/97	Baker et al.	530	305	
JRL	51.	5,707,648	01/13/98	Yiv	424	450	
JRL	52.	5,738,846	04/14/98	Greenwald et al.	424	85.7	
JRL	53.	5,747,445	05/05/98	Backstrom et al.	514	4	
JRL	54.	5,747,642	05/05/98	De Felippis	530	304	

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				Applicants: Ekwuribe et al.			
				Filing Date: August 5, 2002 Concurrently herewith		Group	
JRL	55.	5,750,497	05/12/98	Havelund et al.	514	3	
JRL	56.	5,766,620	06/16/98	Heiber et al.	424	436	
JRL	57.	5,830,853	11/03/98	Backstrom et al.	514	4	
JRL	58.	5,849,860	12/15/98	Hakimi et al.	528	370	
JRL	59.	5,853,748	12/29/98	New	424	439	
JRL	60.	5,854,208	12/29/98	Jones et al.	514	3	
JRL	61.	5,856,451	01/05/99	Olsen et al.	530	402	
JRL	62.	5,866,538	02/02/99	Norup et al.	514	3	
JRL	63.	5,874,111	02/23/99	Maitra et al.	424	499	
JRL	64.	5,898,028	04/27/99	Jensen et al.	514	4	
JRL	65.	5,902,588	05/11/99	Greenwald et al.	424	278.1	
JRL	66.	5,905,140	05/18/99	Hansen	530	303	
JRL	67.	5,922,675	07/13/99	Baker et al.	514	4	
JRL	68.	5,942,248	08/24/99	Barnwell	424	457	
JRL	69.	5,948,751	09/07/99	Kimer et al.	514	4	
JRL	70.	5,952,008	09/14/99	Backstrom et al.	424	499	
JRL	71.	5,952,297	09/14/99	De Felippis et al.	514	3	
JRL	72.	5,962,267	10/05/99	Shin et al.	435	69.4	
JRL	73.	5,968,549	10/19/99	New et al.	424	450	
JRL	74.	5,969,040	10/19/99	Hallahan et al.	525	54.1	
JRL	75.	5,981,709	11/09/99	Greenwald et al.	530	351	
JRL	76.	5,985,263	11/16/99	Lee et al.	424	85.2	
JRL	77.	6,004,574	12/21/99	Backstrom et al.	424	434	
JRL	78.	6,025,325	02/15/00	Campfield et al.	514	2	
JRL	79.	6,034,054	03/07/00	De Felippis et al.	514	4	
JRL	80.	6,043,214	03/28/00	Jensen et al.	514	3	
JRL	81.	6,051,551	04/18/00	Hughes et al.	514	3	
JRL	82.	6,063,761	05/16/00	Jones et al.	514	3	
JRL	83.	6,093,391	07/25/00	Kabanov et al.	424	85.1	

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					Applicants: Ekwuribe et al.			
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84.	6,113,906	09/05/00	Greenwald et al.	424	194.1	
85.	6,165,976	12/26/00	Backstrom et al.	514	3	
86.	6,177,087	01/23/01	Greenwald et al.	424	278.1	
87.	6,191,105	02/20/01	Ekwuribe et al.	514	3	
88.	6,200,602	03/13/01	Watts et al.	424	463	
89.	6,211,144	04/03/01	Havelund	514	4	
90.	6,248,363	06/19/01	Patel et al.	424	497	
91.	6,251,856	06/26/01	Markussen et al.	514	3	
92.	6,258,377	07/10/01	New et al.	424	450	
93.	6,268,335	07/31/01	Brader	514	3	
94.	6,306,440	10/23/01	Backstrom et al.	424	499	
95.	6,310,038	10/30/01	Havelund	514	4	
96.	6,323,311	11/27/01	Liu et al.	530	303	
97.	6,335,316	01/01/02	Hughes et al.	514	3	

FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes- No
98.		GB 1 492 997	11/23/77	Great Britain			
99.		JP 1 254 699	10/11/89	Japan			No
100.		WO 93/01802	02/04/93	PCT			Yes - abstract
101.		EP 0 483 465	08/02/95	EPO			Yes - claims
102.		EP 0 597 007	10/16/96	EPO			
103.		EP 0 621 777	11/09/96	EPO			Yes - claims
104.		EP 0 797 615	01/13/99	EPO			
105.		WO 99/32134	07/01/99	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
106.	Abuchowski, A. and F. F. Davis, "Soluble Polymer-Enzyme Adducts," pp. 368-383, Enzymes as Drugs, J. S. Holcenberg, John Wiley, 1981.	
107.	Akiyama, M. et al., "The Synthesis of New Derivatives of 1-.beta.-D-Arabinofuranosylcytosine," Chem. Pharm. Bull., 1978, 26(3): p. 981-984.	
108.	Allcock et al., "Contemporary Polymer Chemistry," 394-403 (2nd. ed., 1991).	

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109.	Ansell, S. et al., "Application of Oligo-(14-amino-3,6,9,12-tetraoxatetradecanoic acid) Lipid Conjugates as Steric Barrier Molecules in Liposomal Formulations," Bioconjugate Chem., 10: 653-666 (1999).		
110.	Banting et al., "Pancreatic Extracts in the Treatment of Diabetes Mellitus: Preliminary Report," Can. Med. Assoc. J., 145(10): 1281-1286 (1991).		
111.	Baudys et al., "Stabilization and Intestinal Absorption of Human Calcitonin," J. Contr. Rel. vol. 39, pp. 145-51 (1996).		
112.	Baudys, M. et al, "Synthesis and Characterization of Different Glycosylated Derivatives of Insulin" Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater., 1992, 19: 210-211.		
113.	Brange, J., "Galenics of Insulin: The Physico-Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations," Novo Research Institute, Denmark, 18-100 (1987).		
114.	Chen et al., "Synthesis and Properties of AMA Amphiphiles," J. Org. Chem., 64: 6870-6873 (1999).		
115.	Chien, Y. W., Novel Drug Delivery Systems, pp. 678-679, Marcell Deffer, Inc., New York, N.Y., 1992.		
116.	Coombes, A.G.A. et al., "Biodegradable Polymeric Microparticles for Drug Delivery and Vaccine Formulation: the Surface Attachment of Hydrophilic Species Using the Concept of Poly(Ethylene Glycol) Anchoring Segments," Biomaterials, 18: 1153-1161 (1997).		
117.	Coudert et al., "A Novel, Unequivocal Synthesis of Polyethylene Glycols," Synthetic Communications, 16(1): 19-26 (1986).		
118.	Forst et al., "New Aspects on Biological Activity of C-peptide in IDDM Patients," Exp. Clin. Endocrinol. Diabetes, 106: 270-276 (1998).		
119.	Francis et al., "Polyethylene Glycol Modification: Relevance of Improved Methodology to Tumour Targeting," J. Drug Targeting, 3: 321-340 (1996).		
120.	Gombotz et al., "Biodegradable Polymers for Protein and Peptide Drug Delivery," Bioconjugate Chem., 6: 332-351 (1995).		
121.	A. Guzman & R. Garcia, "Effects of Fatty Ethers and Stearic Acid on the Gastrointestinal Absorption of Insulin," PRHSJ, 9(2): 155-159 (1990).		
122.	Harris, J. Milton, "Laboratory Synthesis of Polyethylene Glycol Derivatives," J. Macromol. Science - Rev. Macromol. Chem. Phys., C25(3): 325-373 (1985).		
123.	Hashimoto et al., "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities," Pharmaceutical Research, 6(2): 171-176 (1989).		
124.	Igarashi, R. et al, "Biologically Active Peptides Conjugated with Lecithin for DDS" Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater. 1990, 17 367-368.		
125.	Kemmler et al., "On the Nature and Subcellular Localization of the Proinsulin Converting Enzymes," Federation Proceedings, 30(Abstract 924): 1210Abs (1971).		
126.	Kemmler et al., "Studies on the Conversion of Proinsulin to Insulin: I. Conversion in Vitro with Trypsin and Carboxypeptidase B," The Journal of Biological Chemistry, 246(22) 6786-6791 (November 25, 1971).		
127.	D.G. Lindsay & S. Shall, "The Acetylation of Insulin," Biochem. J., 121: 737-745 (1971).		
128.	Mesiha et al., "Hypoglycaemic effect of oral insulin preparations containing Brij 35, 52, 58 or 92 and stearic acid," J. Pharm. Pharmacol., 33: 733-734 (1981).		
129.	Neubauer et al., "Influence of Polyethylene Glycol Insulin on Lipid Tissues of Experimental Animals," Diabetes, 32: 953-958 (Oct. 1983).		
130.	Nucci, et al. "The Therapeutic Value of Poly(ethylen Glycol)-Modified Proteins" Ac. Drug. Del. Rev. 6: 133-151 1991.		
131.	Patel et al. "Oral Administration of Insulin By Encapsulation Within Liposomes" FEBS Lett. 62(1) 60-63 1976.		

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<i>RL</i>	132.	Russell-Jones, G. J. "Vitamin B12 Drug Delivery", Proceed. Intern. Symp. Control. Rel. Bioactive. Mater., 1992, 19: 102-103.	
<i>RL</i>	133.	Santiago, N. et al, "Oral Immunization of Rats with Influenza Virus M Protein (M1) Microspheres," Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater., 1992, 19: 116-117.	
<i>RL</i>	134.	Savva et al., "Effect of PEG Homopolymer and Grafted Amphiphilic PEG-Palmityl on the Thermotropic Phase Behavior of 1,2-Dipalmitoyl-SN-Glycero-3-Phosphocholine Bilayer," Journal of Liposome Research, 9(3): 357-365 (1999).	
<i>RL</i>	135.	Shen et al., "(C) Means to Enhance Penetration, (3) Enhancement of polypeptide and protein absorption by macromolecular carriers via endocytosis and transcytosis," Advanced Drug Delivery Reviews, 8: 93-113 (1992).	
<i>RL</i>	136.	G. Sirokman & G.D. Fasman, "Refolding and proton pumping activity of a polyethylene glycol-bacteriorhodopsin water-soluble conjugate," Protein Science, 2: 1161-1170 (1993).	
<i>RL</i>	137.	Szleifer, I. et al., "Spontaneous Liposome Formation Induced by Grafted Poly(Ethylene Oxide) Layers: Theoretical Prediction and Experimental Verification," Proceedings of the National Academy of Sciences of the United States of America, 95(3): 1032-1037 (Feb. 3, 1998).	
<i>RL</i>	138.	Taniguchi, T. et al, "Synthesis of Acyloyl Lysozyme and Improvement of its Lymphatic Transport Following Small Intestinal Administration in Rats" Proceed. Intern. Symp. Control. Rel. Bioactiv. Mater., 1992, 19: 104-105.	
<i>RL</i>	139.	V.P. Torchilin, "Immunoliposomes and PEGylated Immunoliposomes: Possible Use for Targeted Delivery of Imaging Agents," Immunomethods, 4: 244-258 (1994).	
<i>RL</i>	140.	Tyle, Praveen, "Iontophoretic Devices for Drug Delivery," Pharma Research, 3:6 318-326 (1986).	
<i>RL</i>	141.	Wahren et al., "Role of C-peptide in Human Physiology," Am. J. Physiol. Endocrinol. Metab., 278: E759-E768 (2000).	
<i>RL</i>	142.	J. Wei & G.D. Fasman, "A Poly(ethylene glycol) Water-soluble Conjugate of Porin: Refolding to the Native State," Biochemistry, 34:6408-6415 (1995).	
<i>RL</i>	143.	Zalipsky et al., "Peptide Attachment to Extremities of Liposomal Surface Grafted PEG Chains: Preparation of the Long-Circulating Form of Laminin Pentapeptide, YIGSR," Bioconjugate Chem. 6: 705-708 (1995).	

EXAMINER
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Jeffrey E. Russell

DATE CONSIDERED

July 18, 2005

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)	Attorney Docket Number 9233-74 (T)	Serial No. 10/018,879 To be assigned
	Applicants: Ekwuribe et al.	
	International Filing Date: June 19, 2000	Group

U. S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
JR	1.	3,256,153	6/1966	Heimlich	167	82	
JR	2.	3,868,356	2/1975	Smyth	260	112.7	
JR	3.	4,003,792	1/1977	Mill et al.	195	63	
JR	4.	4,044,196	8/1977	Hüper et al.	526	271	
JR	5.	4,087,390	5/1978	Shields	260	8	
JR	6.	4,093,574	6/1978	Shields	260	8	
JR	7.	4,100,117	7/1978	Shields	260	8	
JR	8.	4,179,337	12/1979	Davis et al.	435	181	
JR	9.	4,229,438	10/1980	Fujino et al.	424	177	
JR	10.	4,253,998	3/1981	Sarantakis	260	8	
JR	11.	4,277,394	7/1981	Fujino et al.	260	112.5R	
JR	12.	4,410,547	10/1983	Ueno et al.	424	317	
JR	13.	4,585,754	4/1986	Meisner et al.	514	8	
JR	14.	4,622,392	11/1986	Hong et al.	536	29	
JR	15.	4,684,524	8/1987	Eckenhoff et al.	424	469	
JR	16.	4,698,264	10/1987	Steinke	428	402.2	
JR	17.	4,717,566	1/1988	Eckenhoff et al.	424	438	
JR	18.	4,744,976	5/1988	Snipes et al.	424	408	
JR	19.	4,772,471	9/1988	Vanlerberghe et al.	424	450	
JR	20.	4,797,288	1/1989	Sharma et al.	424	476	
JR	21.	4,840,799	6/1989	Appelgren et al.	424	493	
JR	22.	4,849,405	7/1989	Ecanow	514	3	
JR	23.	4,935,246	6/1990	Ahrens	424	490	
JR	24.	4,946,828	8/1990	Markussen	514	3	
JR	25.	4,963,367	10/1990	Ecanow	424	485	
JR	26.	5,013,556	5/1991	Woodle et al.	424	450	

EXAMINER
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DATE CONSIDERED

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office				Attorney Docket Number 9233-74 (1)		Serial No. 10/018,879 To be assigned	
LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)							
Applicants: Ekwuribe et al.							
International Filing Date: June 19, 2000						Group	
27.	5,055,300	10/1991	Gupta	424	409		
28.	5,055,304	10/1991	Makino et al.	424	465		
29.	5,093,198	3/1992	Speaker et al.	428	402.21		
30.	5,164,366	11/1992	Balschmidt et al.	514	3		
31.	5,359,030	10/1994	Ekwuribe	530	303		
32.	5,438,040	8/1995	Ekwuribe	514	3		
33.	5,545,618	8/1996	Buckley et al.	514	12		
34.	5,606,038	2/1997	Regen	536	6.5		
35.	5,681,567	10/1997	Martinez et al.	424	178.1		
36.	5,681,811	10/1997	Ekwuribe	514	8		
37.	5,693,609	12/1997	Baker et al.	514	3		
38.	5,693,769	12/1997	Kahne et al.	536	5		
39.	5,824,638	10/1998	Burnside et al.	514	3		
40.	5,830,918	11/1998	Sportsman et al.	514	648		
41.	5,907,030	5/1999	Shen et al.	530	331		
42.	5,932,462	8/1999	Harris et al.	435	188		
43.	6,309,633	10/2001	Ekwuribe et al.	424	85.1		
FOREIGN PATENT DOCUMENTS							
	Document Number	Date	Country	Class	Subclass	Translation Yes No	
44.	0 031 567 A2	8/1981	EPO	C07C	103/52	Yes	
45.	WO 95/09831	4/1995	PCT	C07C	203/04	Yes	
46.	WO 95/30641	11/1995	PCT	C07C	203/04	Yes	
47.	WO 98/07745	02/1998	PCT	C07K	7/06	Yes	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
48.	Aoshima et al.; "N ⁴ -Behenoyl-1-β-D-Arabinofuranosylcytosine as a Potential New Antitumor Agent" <i>Cancer Research</i> 37 2481-2486 (1977).						
49.	Baker et al.; "Prodrugs of 9-β-D-Arabinofuranosyladenine. 1. Synthesis and Evaluation of Some 5'-(O-Acyl) Derivatives" <i>Journal of Medicinal Chemistry</i> 21:12 1218-1221 (1978).						

EXAMINER
EXAMINER

Jeffrey E. Russel

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		Applicants: Ekwuribe et al.	
		International Filing Date: June 19, 2000	Group

50.	Banting et al.; "Pancreatic Extracts in the Treatment of Diabetes Mellitus" <i>The Canadian Medical Association Journal</i> 12 141-146 (1992).
51.	Boccu et al.; "Pharmacokinetic Properties of Polyethylene Glycol Derivatized Superoxide Dismutase" <i>Pharmacological Research Communications</i> 14:2 113-120 (1982).
52.	Brange et al.; "Chemical Stability of Insulin. 1. Hydrolytic Degradation During Storage of Pharmaceutical Preparations" <i>Pharmaceutical Research</i> 9:6 715-726 (1992).
53.	Brange et al.; "Chemical Stability of Insulin. 2. Formation of Higher Molecular Weight Transformation Products During Storage of Pharmaceutical Preparations" <i>Pharmaceutical Research</i> 9:6 727-734 (1992).
54.	Conradi et al.; "The Influence of Peptide Structure on Transport Across Caco-2 Cells" <i>Pharmaceutical Research</i> 8:12 1453-1459 (1991).
55.	Delgado et al.; "The Uses and Properties of PEG-Linked Proteins" <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 9:3,4 249-304 (1992).
56.	Engel et al.; "Insulin: Intestinal Absorption as Water-in-Oil-in-Water Emulsions" <i>NATURE</i> 219 856-857 (1968).
57.	Fasano, Alessio; "Innovative strategies for the oral delivery of drugs and peptides" <i>TIBTECH</i> 16 152-157 (1998).
58.	Gish et al.; "Nucleic Acids. 11. Synthesis of 5'-Esters of 1- β -D-Arabinofuranosylcytosine Possessing Antileukemic and Immunosuppressive Activity" <i>Journal of Medicinal Chemistry</i> 14:12 1159-1162 (1971).
59.	Hong et al.; "Nucleoside Conjugates. 7. Synthesis and Antitumor Activity of 1- β -D-Arabinofuranosylcytosine Conjugates of Ether Lipids" <i>J. Med. Chem.</i> 29 2038-2044 (1986).
60.	Hostetler et al.; "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides" <i>The Journal of Biological Chemistry</i> 265:11 6112-6117 (1990).
61.	T. King & C. Weiner.; "Preparation of Protein Conjugates with Alkoxypolyethylene Glycols" <i>Int. J. Peptide Protein Res.</i> 16 147-155 (1980).
62.	Maislos et al.; "The Source of the Circulating Aggregate of Insulin in Type I Diabetic Patients Is Therapeutic Insulin" <i>J. Clin. Invest.</i> 77 717-723 (1986).
63.	Oka et al.; "Enhanced Intestinal Absorption of a Hydrophobic Polymer-Conjugated Protein Drug, Smancs, in an Oily Formulation" <i>Pharmaceutical Research</i> 7:8 852-855 (1990).
64.	JC Price; <i>Polyethylene Glycol</i> , 355-361 (Not dated)
65.	Ratner et al.; "Persistent Cutaneous Insulin Allergy Resulting From High-Molecular-Weight Insulin Aggregates" <i>Diabetes</i> 39 728-733 (1990).
66.	Robbins et al.; "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients" <i>Diabetes</i> 36 838-841 (1987).
67.	Saffran et al.; "A Model for the Study of the Oral Administration of Peptide Hormones" <i>Can J. Biochem.</i> 57 548-553 (1979).

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Jeffrey E. Russell

DATE CONSIDERED

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